

**§ 573.800**

roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18282, Apr. 28, 1989]

**§ 573.800 Polyethylene glycol (400) mono- and dioleate.**

(a) The food additive polyethylene glycol (400) mono- and dioleate meets the following specifications: Saponification number, 80–88; acid number, 5.0 maximum; and average molecular weight range, 640–680.

(b) It is used as a processing aid in the production of animal feeds when present as a result of its addition to molasses in an amount not to exceed 250 parts per million of the molasses.

**§ 573.820 Polyoxyethylene glycol (400) mono- and dioleates.**

The food additive polyoxyethylene glycol (400) mono- and dioleates may be safely used as an emulsifier in calf-milk replacer formulations.

**§ 573.840 Polysorbate 60.**

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) It is used alone or in combination with sorbitan monostearate as an emulsifier in mineral premixes and dietary supplements for animal feeds.

(b) It is used as an emulsifier in milk-replacer formulations for calves.

**§ 573.860 Polysorbate 80.**

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate) may be safely used as an emulsifier in milk-replacer formulations for calves.

**§ 573.870 Poly(2-vinylpyridine-co-styrene).**

The food additive poly(2-vinylpyridine-co-styrene) may be safely used as nutrient protectant in feed for beef cattle and dairy cattle and replacement dairy heifers when used in accordance with the following conditions:

(a) The additive meets the following specifications:

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Component/property	Limitation
Inherent viscosity .....	1.0-1.6 deciliter per gram. <sup>1</sup>
Styrene moiety .....	40 percent maximum.
2-Vinylpyridine moiety, .....	90 percent maximum.
Residual styrene .....	200 parts per billion maximum.
Residual 2-vinylstyrene .....	200 parts per billion maximum.
Heavy metals such as lead ....	>10 parts per million.
Arsenic .....	>3 parts per million.

<sup>1</sup> Inherent viscosity of a 0.25 percent (weight/volume) solution in dimethylformamide.

(b) The additive is used in the manufacture of rumen-stable, abomasum-dispersible nutrient(s) for beef cattle and dairy cattle and replacement dairy heifers such that the maximum use of the additive from all sources does not exceed 5.1 grams per head per day. The additive may be used to protect the following nutrients:

(1) *Methionine*. The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of 55 percent methionine by weight. The coated methionine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(2) *Methionine and lysine*. The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of a combined total of 55 percent methionine and lysine by weight. The coated methionine and lysine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(c) *Label and labeling*. To ensure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, feed additive premix, or liquid feed supplement prepared therefrom, shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the following:

- (1) The name of the additive.
- (2) A statement of the concentration of poly(2-vinylpyridine-co-styrene) in any product or mixture.
- (3) Adequate directions for the use of the rumen-stable, abomasum-dispersible nutrient(s) products.

(4) The following statement: “Warning: Maximum use of poly(2-vinylpyridine-co-styrene) from all sources is not to exceed 5.1 grams per head per day.”

[57 FR 7875, Mar. 5, 1992, as amended at 57 FR 24187, June 8, 1992; 61 FR 11547, Mar. 21, 1996]

**§ 573.880 Normal propyl alcohol.**

Normal propyl alcohol may be safely used in feeds and feed supplements for cattle as a source of metabolizable energy. It is incorporated in the feed or feed supplement in an amount which provides not more than 54.5 grams of the additive per head per day.

**§ 573.900 Pyrophyllite.**

Pyrophyllite (aluminum silicate monohydrate) may be safely used as the sole anticaking aid, blending agent, pelleting aid, or carrier in animal feed when incorporated therein in an amount not to exceed 2 percent in complete animal feed.

**§ 573.914 Salts of volatile fatty acids.**

(a) *Identity.* The food additive is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids—isovaleric, 2-methylbutyric, and *n*-valeric.

(b) *Specifications.* The additive contains ammonium or calcium salts of volatile fatty acids and shall conform to the following specifications:

(1) Ammonium salts:

Components	Amount
Ammonium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	48 to 54 percent.
Ammonium salt of isobutyric acid	22 to 26 percent.
Water .....	28 percent maximum.
Ammonia .....	0.3 percent maximum.
Arsenic .....	>3 parts per million.
Heavy metals as lead .....	>10 parts per million.

(2) Calcium salts:

Components	Amount
Calcium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	58 to 72 percent.
Calcium salt of isobutyric acid .....	26 to 34 percent.
Calcium hydroxide .....	3 percent maximum.
Water .....	14 percent maximum.
Arsenic .....	>3 parts per million.
Heavy metals as lead .....	>10 parts per million.

(c) *Use.* The additive is used or intended for use as a source of energy in dairy cattle feed.

(d) *Labeling.* The label and labeling of the additive in any feed, feed supplement, feed concentrate, feed premix, or liquid feed supplement prepared therefrom shall bear, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) Adequate directions for use, including statements expressing maximum use levels. For ammonium salts of volatile fatty acids, the statements: “Not to exceed 160 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.” For calcium salts of volatile fatty acids, the statement: “Not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.”

[49 FR 45125, Nov. 15, 1984; 50 FR 8606, Mar. 4, 1985]

**§ 573.920 Selenium.**

(a) Public Law 103-354 enacted October 13, 1994 (the 1994 Act), states that FDA shall not implement or enforce the final rule issued on September 13, 1993 (58 FR 47962), in which FDA stayed the 1987 amendments and any modification of such rule issued after enactment of the 1994 Act; unless the Commissioner of Food and Drugs makes a determination that:

(1) Selenium additives are not essential at levels authorized in the absence of such final rule, to maintain animal nutrition and protect animal health;

(2) selenium at such levels is not safe to the animals consuming the additive;

(3) selenium at such levels is not safe to individuals consuming edible portions of animals that receive the additive;

(4) selenium at such levels does not achieve its intended effect of promoting normal growth and reproduction of livestock and poultry; and

(5) the manufacture and use of selenium at such levels cannot reasonably be controlled by adherence to current good manufacturing practice requirements.